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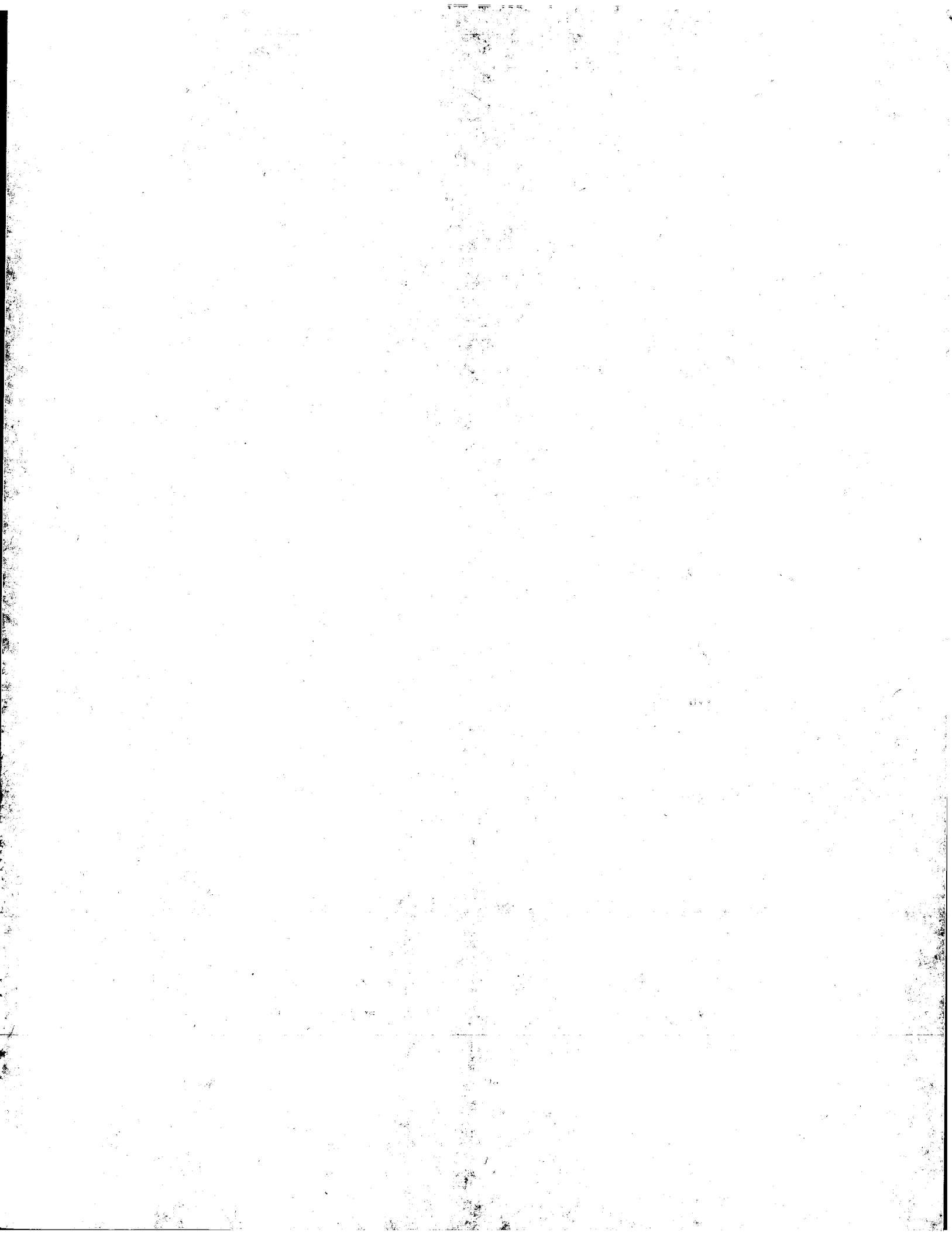
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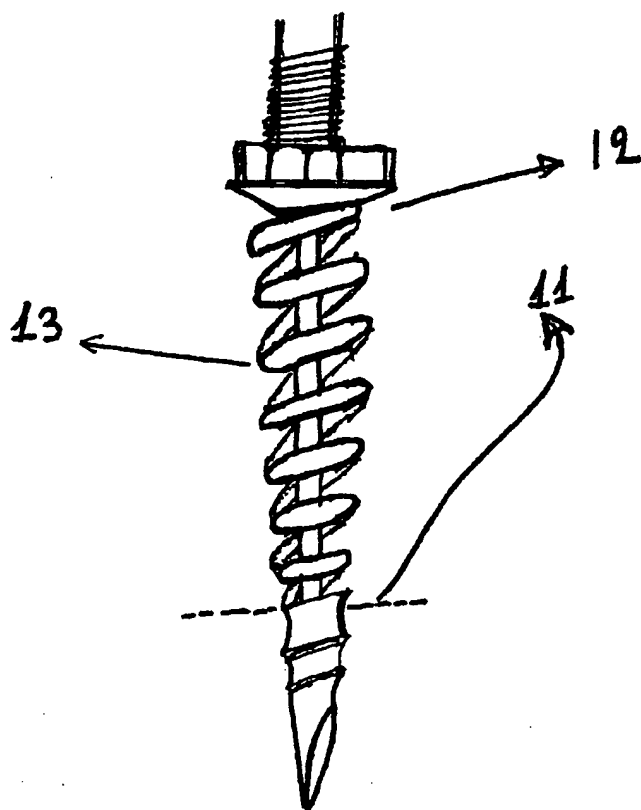
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(54) Title: POSTERIOR FUSION SYSTEM OF PEDICLE SCREW-ROD-CONNECTOR



(57) **Abstract:** Posterior fusion system, screw-rod-connector, whose screw the body that is screwed in the bones is characterized by clockwise threads, helical attached to an anti-clockwise rotating central spring consisting of a core and anti-clockwise wings. The screw functions as an implant, since it is incorporated in the surrounding spongiosa bone completely, with the two rotated at 180 degrees helical compartments that allow communication and contact in a 360 degrees direction. Its front section is hollow and slightly pointed. Its connection is accomplished with a joint and divisible rod with free movement before the nut's final tightening, separately for each vertebra, thanks to two receptions of the joint and the rod's spherical heads. This eases the placement and also the rod's application without any tension and after tightening the nut it immobilizes it in any position and allows all reduction handling, before the final tightening. The whole system assembled in this way and with a flexible screw, which withstands more fatigue than the solid one, is incorporated much faster because the screw acts as an implant and thus withstands more fatigue. Finally, it increases the construction's longevity, reducing loosening danger from the implantation site.

WO 02/24087 A1

WO 02/24087 A1

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WO 02/24087

1

PCT/GR01/00036

POSTERIOR FUSION SYSTEM OF PEDICLE SCREW-ROD-CONNECTOR

5 TERMS TO BE USED

Human Spine (H.S.), implant-pedicle screw, joint, divisible rod, helical spring

TECHNICAL FIELD

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The posterior fusion systems are generally used in the stabilization of the Human Spine, in fractures, degenerative spine diseases, and deformities that cause various functional, neurological problems, etc. The materials are screws that pass through the vertebrae's pedicles, two per vertebra and are connected to one another onto a rod
15 with the use of a joint. These three elements, that is the screw, the rod or plate, and the joint which connects them combined with the specific properties that they have due to their design, which differs from system to system, also characterize the ability of each system that is in use nowadays to be easily positioned, while correcting, reducing, and at the same time retaining such mechanical and bio-mechanical
20 properties after its application, increasing the material's endurance to breaking and fatigue, or reducing as much as possible failure danger due to screws' loosening and migration (pull out).

PREVIOUS TECHNIQUE'S LEVEL

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Today there exist various screws and joints that connect them to rods or plates hence creating a short or longer construction, depending on the situation and the stabilization need that is demanded. In almost all systems that exist, the rods used are of the same diameter, usually of 6 mm and onto them slip the joints that are designed in such a
30 way so that they easily sit on the screw's threaded upper section, and then are secured with a nut, allowing the creation of a construction of whatever length, that may start from the first thoracic vertebrae and end up low to the sacral bone. Hence, it stabilizes the H.S. to all its length. There is no positioning or application difficulty in

WO 02/24087

2

PCT/GR01/00036

short constructions. However, the longer the construction the more difficulties may occur especially in their assembly, either due to the fact that the screws are not in the same straight line that is they are in different distances from the rod but they also form different angles on the sagital and transverse axis, the joint's hole doesn't always sit on the screw's threaded upper part and exercise of force is necessary. In order to solve this difficulty and succeed to the construction's assembly without tension, screws whose head can move by 10 or 15 degrees towards any direction of 360 degrees have been designed, or joints that also have double movement both towards the rod and the screw too. Although this technique solves most of the problems, in lots of cases and mostly in heavy deformity, kyfosis, scoliosis, and angle formation due to trauma etc., the abilities of these techniques are not enough and further bending of the rod is demanded at the points where the rod's joint does not come close enough to the screw in the correct way. Such points are the peaks of the convex or the ends of the construction. The rod is pre-bent so that it follows the proportional convexities of H.S., before its application, but it is also bent afterwards, after assembly on the H.S. in order to achieve the corrections that we want, such as derotation of scoliosis, reduction (elevation) etc. These operations result in assembling the whole construction under tension, although care is taken in order to avoid the appearance of these forces because they are the main cause of the material's failure, either due to breakage due to fatigue, or due to the implanted screws' loosening inside the bone. In order to avoid the phenomenon of loosening, screws with bio-mechanical properties have been designed so that they promote osteogenesis since they are covered with porous titanium and are of conical shape etc, and instead of a metallic rod of 6 mm that connects them, 2 thinner ones that offer elasticity are used or a rod made of polyurethane.

ADVANTAGES OF THE NEW TECHNIQUE

The new technique is based on improvements of the biomechanical behavior of the points that used to be the main cause of total or partial failure of the fusion's materials. The screw has been designed so that on the one hand it is not as rigid as in all other systems and on the other hand it functions with implant's characteristics. Hence, it is fully embodied in the bone where it is implanted. Its body's elasticity

WO 02/24087

PCT/GR01/00036

3

allows the absorption of the vibration loads that are responsible either for the fatigue and breakage or for the screw's loosening in the implantation site, since micro-movements can smoothen and destroy the walls (threads) of the bone's hole where it is screwed. The screw's design with a hollow front section and S shaped helical
5 spring, which rotates itself at 180 degrees anti-clock wise, to all its length, pushing in its interior, the pieces of bone that it cuts into when it is being screwed clockwise, fills the internal section of the threads with the same bone where it is being implanted. This significantly reduces the demanded time for osteogenesis and its attachment on its touch points.

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On the contrary, all solid screws during screwing, push and put aside the bone perimetrically, without embodying it in their interior, which does not allow the communication among its diametrically opposite sections, that's why screws of this type, contrary to ours, are not characterized as implants. This combined with the
15 exercise of loading forces or even due to permanent tension of the construction's application in some cases, results in partial or total failure with loosening or breakage.

The connection of the screw to the rod is performed in whichever position without any tension because the rod is not solid, but divisible, thanks to the joint's mechanism
20 which before tightening the nut allows movement towards all directions. Depending on the number of vertebrae we wish to fuse, we add the demanded rods, one after the other, easily by opening the joint which accepts the spherical end of the rod in its two reception points, thus increasing the construction's length while tying the screws without demanding application of force or tension and contrary to the existing
25 technique which in most cases demands the rod's bending so that the joint will be attached to the screw.

Our system has an advantage after implantation and positioning of the whole construction compared to the existing technique, when after the assembly we perform
30 corrective maneuvers in order to bring the H.S. back to its normal height, correct kyfosis-angle formation, or derotate the scoliosis. The divisible rod is a very important advantage especially in cases where we have to tie many vertebrae, making long constructions, since step by step and trough exercise of minimal force we succeed in gradual correction, contrary to the previous technique that is based on the

WO 02/24087

4

PCT/GR01/00036

pre-bent rod, which demands great force to be exercised hence causing the screw to be pulled out of position or breaking of the bone (pedicle).

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DESCRIPTION

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In a few words the figures represent the stages as follows:

Fig. 1 shows the screw with the thread of different design. Fig. 2 shows the internal helical spring of the screw in a vertical cut, together with part of the thread. Fig. 3 shows the lower hollow end of the screw. Fig. 4 shows the rod with the two elliptic spheres on its edges. Fig. 5 shows the joint open and fig. 6, shows it closed having engulfed the two ball-shaped ends inside the special upper and lower cavities of the rod. Fig. 7 shows the screw tied to the rods and the nut secured. Fig. 8 shows the whole construction in position. Fig. 13 shows the helical internal spring 10 along the screw.

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It is about a posterior Lumbar fusion system which consists of screw-implant, rod, and joint with the following characteristics:

The screw fig. 1 is hollow on its end while it is of oblique and sharp end fig. 3, so that it cuts easily through the bone. While it is clockwise advanced with the screwdriver, the cut bone is gathered by the anti-clockwise 180 degrees helical spring 10 fig. 2, which starts after point 11, fig.1, continues up to the screw's head 12 fig. 1 and forms its internal structure, which is complemented by the perimetrical threads 13, that create two cavities, rotated around themselves at 180 degrees anti-clock wise, to all the length of the helical spring, 20 and 21 fig. 2. The threads 13 fig. 1 lean and are attached on the helical spring. The screw's body can be seen on fig. 2, where the spring's 10 structure consisting from nucleus 22 is also visible on fig. 2, together with the two wings of opposite direction 24 that have anti-clockwise orientation, so that

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WO 02/24087

PCT/GR01/00036

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they help in forwarding the bone towards the upper section of the screw.

Compartments (cavities) 21 and 22 fig. 2 that are created from the 180 degrees rotation of the spring 10, which is also the body of the screw, in the space and from the two tangent threads. Thus the screw's body is not solid but helical and with the

5 threads, on its perimeter, creates the two compartments 21 and 22 fig. 2 that are filled with cut bone that was cut from the front part of the screw after the final screwing, and communicate directly towards all directions perimetrically to the screw with the neighboring bone tissue of the pedicle and the vertebra towards 360 degrees. This creates the best possible conditions for the incorporation of the screw and ossification

10 and makes it differ from the solid ones that exist nowadays, so that it can be characterized as screw-implant. For the connection of the screw to the rods, a joint fig.5 is used, open fig.9 and closed fig. 6 which accepts the spherical ends of the rods, which (joint) that carries mechanism 26 fig. 9 on one of its sides so that it can open and close. The threaded stem of screw 14 fig. 7, passes through the joint's hole 15

15 fig.5 and then we close the joint having previously placed in cavities 17, the spherical heads of the construction's two rods, in such a way so that notch 16, sits on the stem 14, on whose end we screw nut 19 in order to secure the connection as can be seen on fig. 7. On fig. 10 the rod's head 40 can be seen, it is placed on the two ends of the construction on the external side of the reception 17 fig. 5, unless a transverse bridge

20 44 fig. 11 is needed to be placed for better support and stability in rotational forces. The joint's hole 15 fig. 5, is not round but oblong, so that we can tighten the screw on either side, in order to correct if needed and regain the gap's lost height, through increasing or decreasing the distance between the two screws and through the selecting a rod of an appropriate length.

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EXAMPLE

On a patient with compression fracture of the body of the 3rd Lumbar vertebra, which results in loss of height, we insert the screws of fig. 1 in the pedicles of L2, L4, L5, on

30 both sides of the injured vertebral body, having previously catheterized them with a thin drill, keeping in mind the differences of the angles that exist proportionally to the vertebra's height, on sagittal and transverse axis, in order to avoid injuring the root or the spinal channel. We then place the rods having chosen the appropriate length so

WO 02/24087

6

PCT/GR01/00036

that their spherical ends sit on the receptions of the joints, so that when we close the joint the hole 15 fig. 5 accepts first the stem of the screw 14, fig. 7 onto which the nut 19 will be secured without being tightened. On the two ends of our construction, that is on L2 on its upper and the lower section of L5 we place a spherical head 40, fig. 10, so that there is symmetry of exercise of force during the nut's tightening.

Having placed the construction assembled but keeping nuts 19 loose and before the final tightening, we can attempt easy reduction of the kyfosis and restoration of the height of the inter-vertebral space back to normal by exercising force on all three axes of space. The oblong shape of the joint's 15 hole, allows correction, increase or reduction of the neighboring screws' in-between distance up to 2.5 cm, which allows the easy elevation of the space's height.

After the final tightening of nuts, we move on stitching and closing the trauma.

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WO 02/24087

7

PCT/GR01/00036

CLAIMS

5 1. Posterior fusion system, consisting of screw-rod-connector, which is characterized by the fact that the screw carries threads 13, attached onto a 180 degrees helical rotating central spring 10, which forms the body of the screw, consisting of a core 22 and wings 24 fig. 2 of anti-clockwise direction, creating two 180 degrees helically rotating compartments 20 and 21, the spring starts from end 11 and after being rotated
10 around its axis symmetrically by 180 degrees, ends up on point 12 of the screw's head fig. 1 whose lower end is hollow and pointed fig. 3 and 1 which is connected to a joint fig. 5, which carries two receptions for the spherical heads of the rod, the hole 15 into which the nut that secures the two rods and the screw, is oblong of oval shape, so that we can tighten the nut on its upper either its lower end. In this way, and by choosing
15 rod 40 of appropriate length, we can increase or decrease the distance, reduce the H.S.'s height and ease the execution of the system's assembly.

2. Posterior fusion system, consisting of screw-rod-connector, which is characterized by the fact that the screw carries threads 13, attached onto a 180 degrees helically
20 rotating central spring 10 consisting of a core 22 and wings 24 fig. 2 of anti-clockwise direction, creating two 180 degrees helically rotating compartments 20 and 21, the spring starts from end 11 and after being rotated around its axis symmetrically by 180 degrees, ends up on point 12 of the screw's head whose lower end is hollow and pointed fig. 3 and 1 which is connected to a joint fig. 5, which carries two receptions
25 for the rod's spherical heads and an oblong hole 15 into which we screw and tighten the nut which secures the two rods and the screw, whose rod-screw connector opens and closes with a hinge-like mechanism 26 fig. 9.

3. Posterior fusion system, consisting of screw-rod-connector, which is characterized
30 by the fact that the screw carries threads 13, attached onto a 180 degrees helical anti-clockwise rotating central spring 10, which the body of the screw, the spring consists of a core 22 and wings 24 fig. 2 of anti-clockwise direction, creating two 180 degrees helical rotating compartments 20 and 21, the spring starts from end 11 and after being

WO 02/24087

8

PCT/GR01/00036

rotated around its axis symmetrically by 180 degrees, ends up on point 12 of the screw's head fig. 1, whose lower end is hollow and pointed, fig. 3 and 1, which is connected with joint fig. 5, that carries two receptions for the rod's spherical heads and an oblong hole 15 onto which the nut is screwed and tightened securing the two rods and the screw, whose oblique cut end, is hollow and open at the front so that
5 when screwed it takes inside bone pieces that are then forwarded by the spring 10 towards the upper part of the compartments 20 and 21 fig. 2.

4. Posterior fusion system, consisting of screw-rod-connector, which is characterized
10 by the fact that the screw carries threads 13, attached onto a 180 degrees helical rotating central spring 10, which is the body of the screw, consisting of a core 22 and wings 24 fig. 2 of anti-clockwise direction, creating two 180 degrees rotating compartments 20 and 21, the spring starts from end 11 and after being rotated symmetrically around its axis by 180 degrees, ends up on point 12 of the screw's head
15 fig. 1 whose screw's the lower end is hollow and pointed, fig. 3 and 1, which is connected with joint fig. 5, which carries two receptions for the spherical heads of the rod, onto which the nut that secures two rods with the screw is screwed, through which the screw's stem 14 passes where the nut is screwed and tightened securing two rods and the screw, whose rods have spherical ends but of elliptic shape, and not of a
20 complete sphere, fig. 6.

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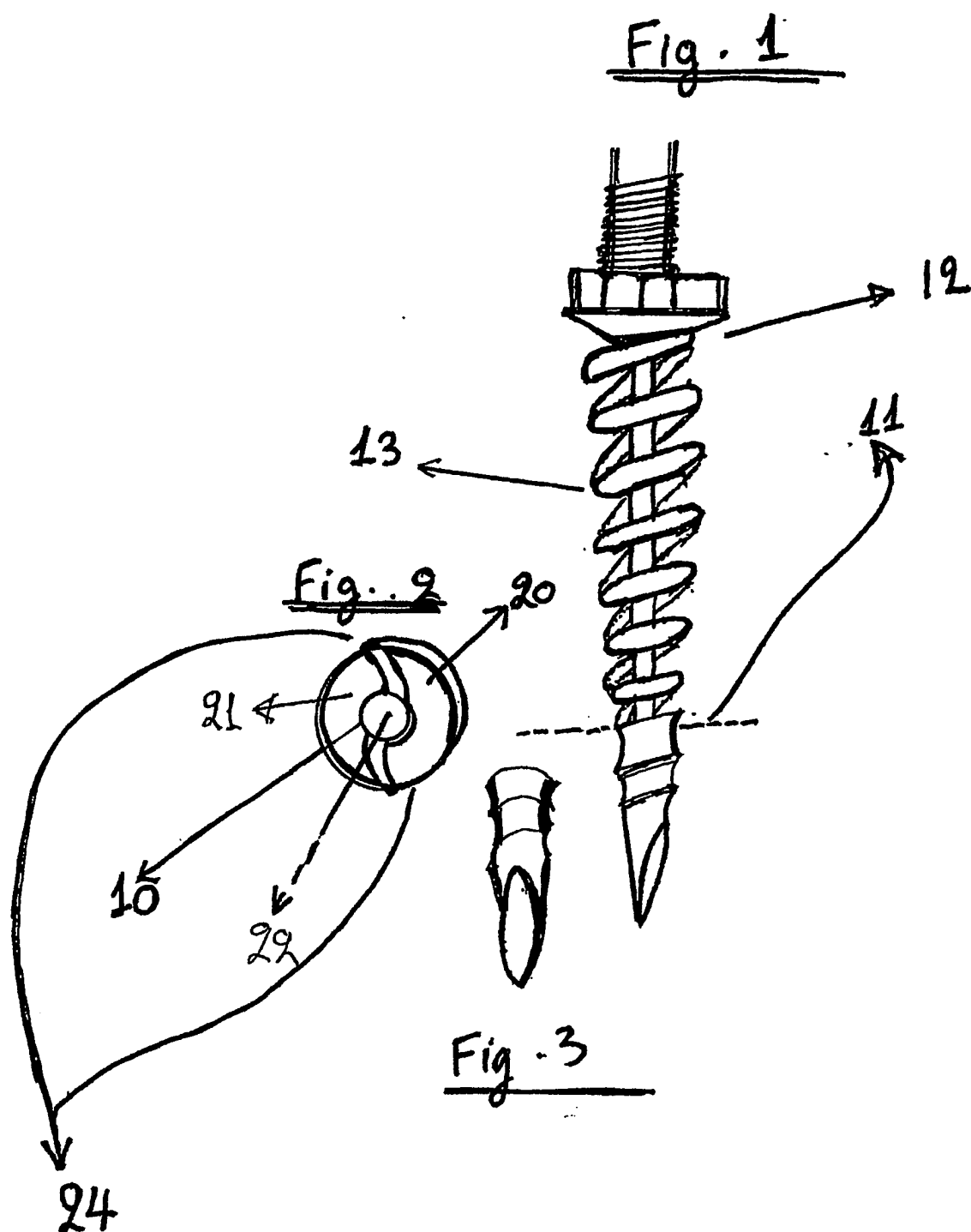
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WO 02/24087

1/4

PCT/GR01/00036



WO 02/24087

2/4

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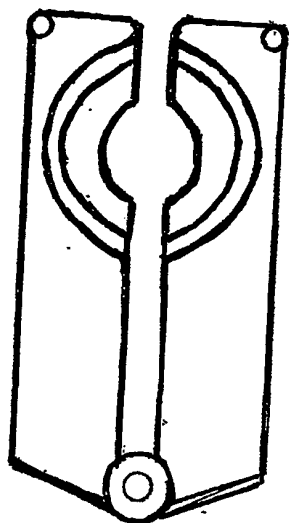


Fig. 9



Fig. 4

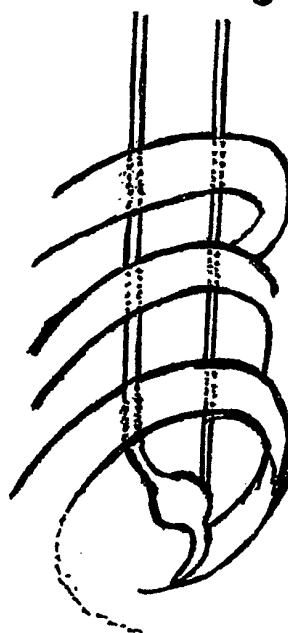


Fig. 13

WO 02/24087

PCT/GR01/00036

3/4

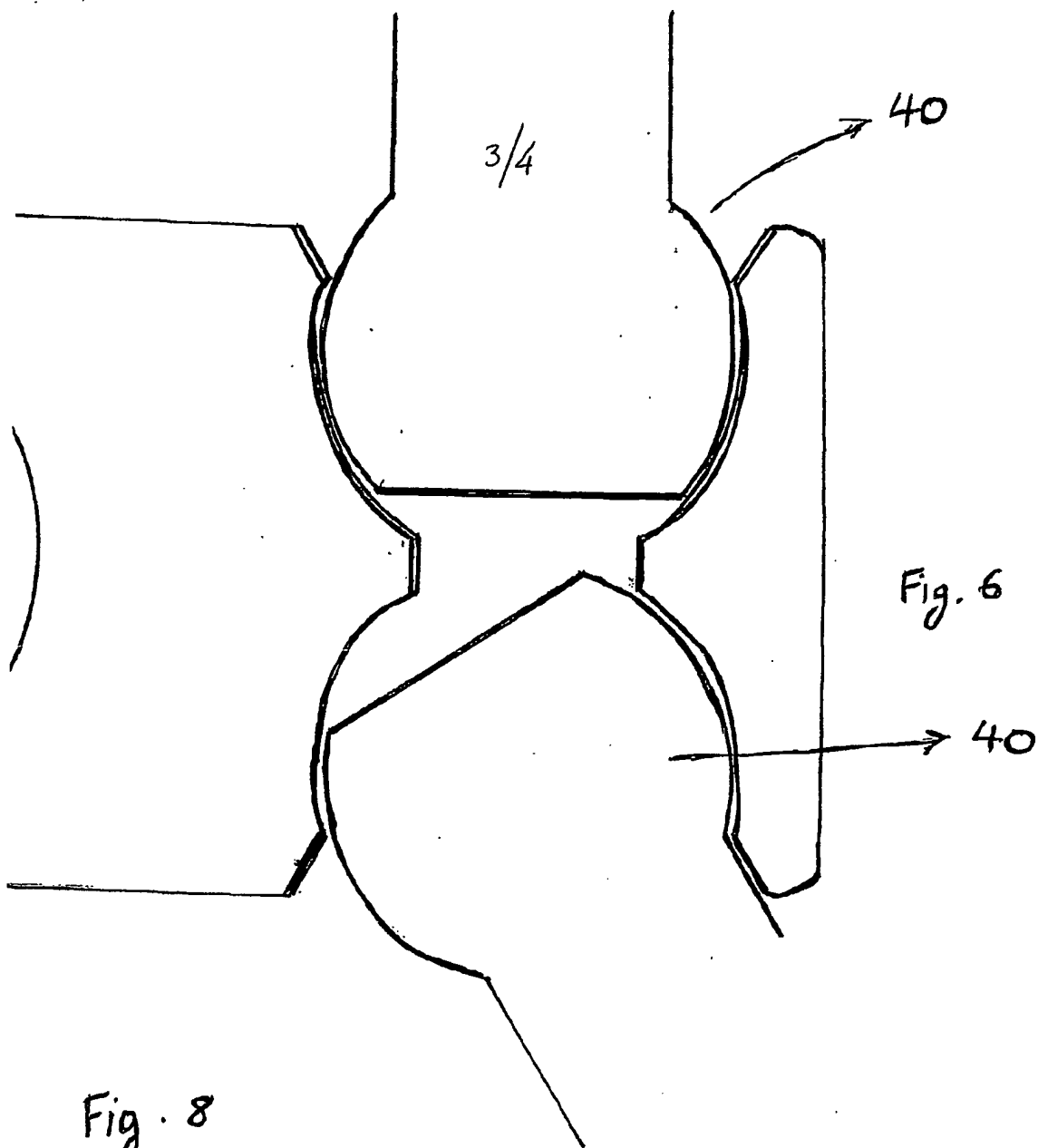
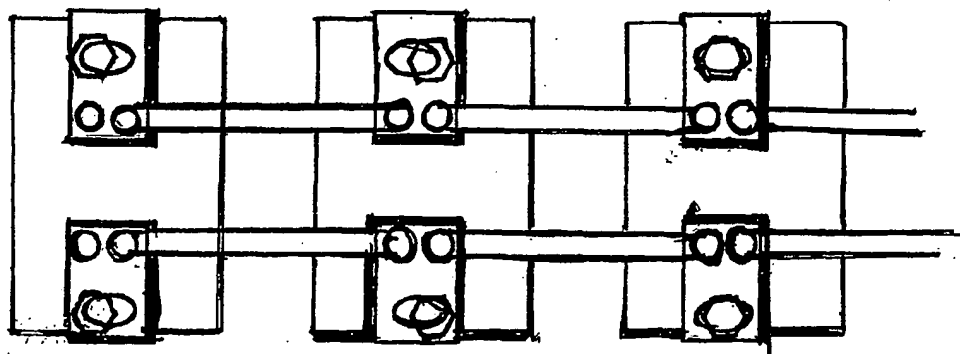


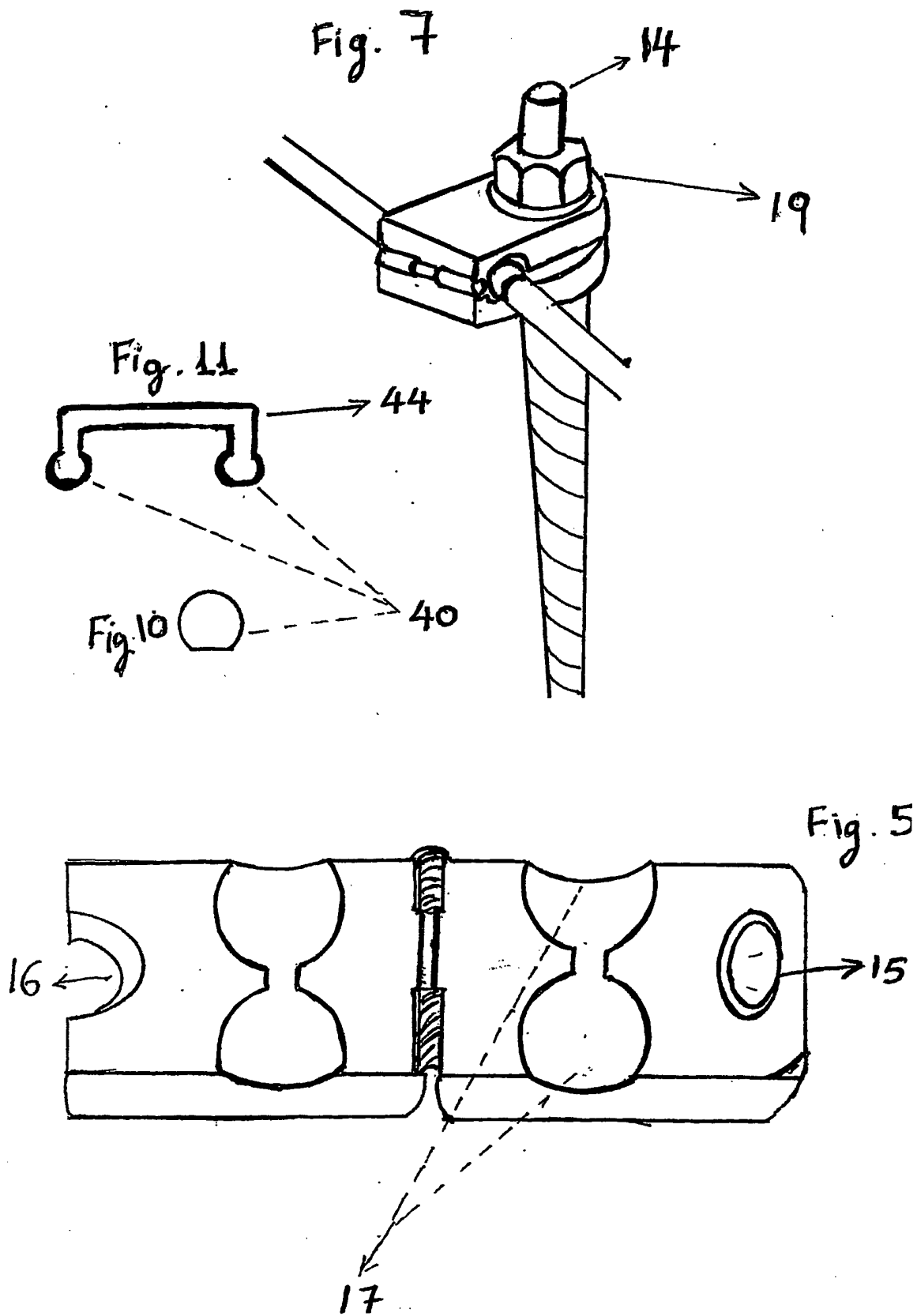
Fig. 8



WO 02/24087

4/4

PCT/GR01/00036



INTERNATIONAL SEARCH REPORT

International Application No

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 298 18 831 U (AESCULAP) 24 December 1998 (1998-12-24) figures	1-4
A	US 5 704 936 A (MAZEL) 6 January 1998 (1998-01-06) figures	1-4
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Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
DE 29818831	U	24-12-1998	DE 29818831 U1	24-12-1998
US 5704936	A	06-01-1998	FR 2689750 A1	15-10-1993
			AU 3957493 A	18-11-1993
			CA 2133766 A1	28-10-1993
			DE 69314334 D1	06-11-1997
			DE 69314334 T2	12-03-1998
			EP 0634911 A1	25-01-1995
			ES 2109488 T3	16-01-1998
			WO 9320771 A1	28-10-1993
			JP 2642516 B2	20-08-1997
			JP 7501735 T	23-02-1995
US 5843082	A	01-12-1998	AU 705957 B2	03-06-1999
			AU 1916097 A	04-12-1997
			CA 2203584 A1	30-11-1997
			EP 0809973 A2	03-12-1997
			JP 10057395 A	03-03-1998
			KR 211196 B1	15-07-1999
			US 6036693 A	14-03-2000